



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,395	04/02/2001	J. Milton Harris	44646/214160	1903

826 7590 11/13/2002

ALSTON & BIRD LLP  
BANK OF AMERICA PLAZA  
101 SOUTH TRYON STREET, SUITE 4000  
CHARLOTTE, NC 28280-4000

[REDACTED] EXAMINER

NAFF, DAVID M

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1651

DATE MAILED: 11/13/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/624395	Applicant(s)	thomas et al
Examiner	Acuff	Group Art Unit	1451

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 9/12/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 1 1; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 1 - 27 is/are pending in the application.
- Of the above claim(s) 1, 3 + 8 - 21 is/are withdrawn from consideration.
- Claim(s) 27 is/are allowed.
- Claim(s) 2, 4, 5 + 7 is/are rejected.
- Claim(s) 6 + 28 is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

## Office Action Summary

The amendment of 9/12/02 has been entered. The amendment added claims 26 and 27.

Claims 1, 8-11 and 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, 5 there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7 (filed 12/21/01).

Claim 3 and 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in 10 Paper No. 7.

Claims examined on the merits are 2 and 4-7, 26 and 27.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 26 is objected to under 37 CFR 1.75 as being a substantial 15 duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

20 **Claim Rejections - 35 USC § 103**

Claims 2, 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al in view of Greenwald et al for the type of reasons set forth in the previous office action of 3/12/02 and reiterated below.

The claims are drawn to a heterobifunctional acrylate of poly(alkylene oxide) having in the backbone a linkage that is hydrolytically degradable.

Yang et al discloses a heterobifunctional poly(ethylene glycol) 5 having an acrylate group on one terminus and an activated carboxylic acid on the second terminus, and attaching this PEG derivative to a protein.

Greenwald et al disclose a prodrug composition containing a hydrolyzable linkage such as an ester linkage between a polymer portion and a biologically active moiety for release of the biologically active 10 moiety (paragraph bridging cols 4 and 5). The polymer may be PEG-acid or PEG-diacid having the hydrolyzable linkage (col 7, lines 1-15 and col 12, lines 20-61).

It would have been obvious to provide a hydrolyzable linkage in the backbone of the heterobifunctional poly(ethylene glycol) of Yang et al to 15 obtain the function of the linkage to enable releasing a biologically active moiety attached to the heterobifunctional poly(ethylene glycol) as suggested by Greenwald et al using PEG containing a hydrolyzable linkage for release of an attached biologically active moiety. The modifications required by claims 4, 5 and 7 would have been matters of obvious choice 20 within the skill of the art in view of Yang et al and Greenwald et al.

Applicant's arguments filed 9/12/02 have been fully considered but they are not persuasive.

Applicants urge that there is no suggestion in Greenwald et al to incorporate a hydrolyzable linkage in the backbone of the polymer of Yang 25 et al rather than between the biologically active group and the polymer.

However, to place the hydrolyzable group in the polymer backbone would have been merely a matter of obvious choice depending on individual preference. No unexpected result is seen in the hydrolyzable group being in the polymer backbone. The hydrolyzable group could be in the backbone 5 near the end of the backbone which would be little different than having the hydrolyzable group attached to the end of the backbone. It would have been expected that the ester linkage of Greenwald et al could be in the polymer backbone in view of Greenwald et al disclosing (col 7, lines 1-10) that bis-activated polyethylene oxides can be used, and to obtain 10 the hydrolyzable linkage mono- or di-acid activated polymers such as PEG acids or PEG diacids can be used. To provide the ester group in the backbone would merely require coupling a PEG acid to a PEG-OH which would have been obvious.

Claims 6 and 26 are free of the prior art.

15 Claim 6 is objected to as being dependent on a rejected claim.

Claim 27 is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set 20 to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, 25 and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from

the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications 5 from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a 10 message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or 15 (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651

DMN  
11/12/02